

February 6, 2016

Senator Charles Grassley
Senator Ron Wyden
Senate Finance Committee
United States Senate
Washington, DC 20510

Dear Senators:

Congratulations on your public service in publishing “The Price of Solvaldi...” Also, thank you for the excellent questions contained in your open letter of January 21, 2016.

I urge you to consider re-establishing a Renegotiation Board designed to promote drug development at a reasonable cost to society.

As you know, between 1942 and 1979, largely under the jurisdiction of Senate Finance and House Ways and Means, there was a Renegotiation Board-type operation designed to protect the public against war profiteering and cost overruns in the vital defense/weapons industries. It was not a perfect organization—what is?—but it saved the taxpayers billions and billions of dollars and helped re-assure the public that defense contractors—whose novel and hard-to-price products we desperately needed--were accountable.

The Renegotiation Board traces to a 1942 amendment when the Nation vitally needed weapons—including new weapons on which no one had any idea what the costs of production would be—delivered a.s.a.p. The Board was continued as the Cold War developed, then Korea, then Vietnam. Throughout the era, the Nation needed to buy weapons of unprecedented complexity and cost. The Renegotiation Board was a retroactive review of these trillions of dollars in defense contracts to ensure that profiteering was minimized.¹

I have heard that Eisenhower once said, “I am for profits, not profiteering”—the purpose of the Renegotiation Board. And of course he warned of the military-industrial complex—a complex now dwarfed in size of GDP by the health industrial complex.

A Renegotiation Board-type proposal could ensure the profits needed to cure diseases without the gross excesses we've seen in recent years. The extraordinary monopoly price gouging by almost research-free companies would be eliminated and resources directed to more research and/or lower consumer prices.

Like defense weapons, health tools are essential. I urge you to view medicines as you would a utility: medicines and devices are the future of health care and like water, gas, and electricity, they need to be produced efficiently and available to all the public (and for those with low-incomes, through taxpayer-affordable public assistance programs).

A several member, bipartisan or non-partisan Renegotiation Board would review profits and projected

¹For some quick review of the Board, see past Joint Committee on Taxation reports and The American University Law Review (Vol. 24:339), Judith Ann Yannello, “Judicial Proceedings in Renegotiation Act Cases.”

income streams versus reasonable expenses; profiteering would be subject to an excess profits penalty. The very threat of such a penalty would almost certainly stop some of the breath-taking launch prices we are now seeing (or cause pricing to come down dramatically once R&D costs were recovered). ²

But more importantly, under your legislative direction, the Board could adjust its definition of profits to encourage re-investment of profits, not in advertising and sales or excessive compensation, but in research, with special allowance for research on rare and life-threatening diseases and breakthrough products (as designated by the FDA). Under your direction, the Board could encourage re-investment in other things we need the drug and device industries to be doing:

- post-market safety surveillance for the many drugs and devices approved on a fast-track basis or on the basis of surrogate endpoints;
- sound randomized clinical control trials on off-label uses to ensure that drugs used off-label actually have science to support such use;
- higher company-wide profit rates for those who incur the cost of developing superior antibiotics but truly restrain their use;
- denial of costs (or penalties on profits) for slowing or delaying the entry of generics;
- higher profits on very low cost generics and off-patent products where we are seeing production shortages and disruption of supply.

And of course, lower profits could be allowed on me-toos; profits on high-priced drugs found, over time, to be ineffective could be reduced; and deductions against income could be denied for failure to meet legal requirements (for example, the cost of a trial which is not registered with NIH's website).

In sum, just as Senate Finance refined the Renegotiation Board over the years—and kept it on a short leash of renewals--you could refine this proposal to answer the questions posed in your letter and report.

Past excesses have caused many Americans to distrust this industry and the political system that permits these excesses. A Renegotiation Board-type proposal could help save the industry from Draconian proposals, and steer profiteering toward reinvestment into the life-saving cures we all desire.

Thank you for your consideration.

Sincerely,

William Vaughan

²As a health aide with the Ways and Means Committee, over 25 years ago I was involved in my employer's questioning of the launch price of a new drug that greatly increased Medicare costs. The company reported that it recovered its entire R&D costs within nine months of Medicare payments. The Medicare billions and billions it collected in the following years were not clearly used well to benefit health care, in my opinion.